Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

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K093428 (1/2)

DEC 17 2009

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

510(k) Submission for the Smith & Nephew Knotless Instability Anchor

Date Prepared: October 30, 2009

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Kathy Reddig
Regulatory Affairs Specialist II
978-749-1321 Phone
978-749-1443 Fax

C. Device Name

Trade Name: Smith & Nephew Knotless Instability Anchor

Common Name: Fastener, Fixation, Non-degradable, Soft Tissue

Classification Name: Smooth or threaded metallic bone fixation fastener

D. Predicate Devices

The Smith & Nephew Knotless Instability Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: Smith & Nephew BIORAPTOR 2.3PK , Smith & Nephew TwinFix PK FP, and the Mitek BioKnotless anchor.

E. Description of Device

The Smith & Nephew Knotless Instability Anchor is a tap in anchor that is manufactured from PEEK and comes pre-assembled on an inserter, sized appropriately to facilitate both hip and shoulder procedures. The device allows for knotless tissue attachment and reapproximation in surgical repairs of soft tissue to bone.

F. Intended Use

The Smith & Nephew Knotless Instability Anchor is intended for use in the attachment or reattachment of soft tissue to bone for the following indications:

Hip
Hip capsule repair (Acetabular labrum reattachment)

Shoulder
Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs, Biceps tenodesis

Foot and Ankle
Hallux valgus repairs, Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon, repairs/reconstructions, Bunionectomy

Elbow, Wrist, and Hand
Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair

Knee
Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquous advancement), Iliotibial band tenodesis

G. Comparison of Technological Characteristics

The Smith & Nephew Knotless Instability Anchor is substantially equivalent in intended use, technological characteristics, and are as safe and as effective as their currently marketed predicate devices, the Smith & Nephew BIORAPTOR 2.3PK(K071586), the Smith & Nephew TwinFix FootPrint PK(K073509), and the Mitek BioKnotless(K002639).

H. Summary Performance Data

The performance testing demonstrates that the biomechanical parameters of the Smith & Nephew Knotless Instability Anchor are substantially equivalent to the corresponding parameters of the Smith & Nephew BIORAPTOR 2.3PK(K071586), the Smith & Nephew TwinFix FootPrint PK(K073509), and the Mitek BioKnotless (K002639).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith and Nephew Endoscopy, Inc.
% Ms. Kathy Reddig
Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

DEC 1 7 2009

Re: K093428
Trade/Device Name: Smith & Nephew Knotless Instability Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: October 30, 2009
Received: November 3, 2009

Dear Ms. Reddig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093428

Device Name: **Smith & Nephew Knotless Instability Anchor**

Indications For Use:

The Smith & Nephew Knotless Instability Anchor is intended for the reattachment of soft tissue to bone for the following indications:

Hip
Hip capsule repair
- Acetabular labrum reattachment

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromioclavicular separation repairs
Deltoid repairs
Rotator Cuff repairs
Biceps Tenodesis

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Knee
Extra-capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs
- Vastus medialis obliquous advancement

Iliotibial band tenodesis

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093428